DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 26, 2015

BSN medical GmbH
% Ms. Marcia Palma
NAMSA
4050 Olson Memorial Highway, Suite 450
Minneapolis, Minnesota 55422

Re: K143151
Trade/Device Name: Cutimed® Sorbact® Wound Dressing (Cutimed® Sorbact® Hydroactive, Cutimed® Sorbact® Hydroactive B, Cutimed® Sorbact® Siltec Sorbact)
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 1, 2014
Received: November 4, 2014

Dear Ms. Palma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K143151

Device Name
Cutimed® Sorbact® Wound Dressings (Cutimed® Sorbact® Hydroactive, Cutimed® Sorbact® Hydroactive , Cutimed® Siltec Sorbact®)

Indications for Use *(Describe)*

Cutimed® Sorbact® Hydroactive is indicated for use in the management of low to moderate exuding partial to full thickness wounds (including clean, colonized, contaminated, or infected wounds): chronic wounds (venous and arterial ulcers, diabetic ulcers and pressure ulcers), postoperative dehisced wounds and traumatic wounds.

Cutimed® Sorbact® Hydroactive B is indicated for use in the management of low to moderate exuding partial to full thickness wounds (including clean, colonized, contaminated, or infected wounds): chronic wounds (venous and arterial ulcers, diabetic ulcers and pressure ulcers), postoperative dehisced wounds and traumatic wounds.

Cutimed® Siltec Sorbact® is indicated for use in the management of moderate to heavily exuding partial to full thickness wounds (including clean, colonized, contaminated, or infected wounds): chronic wounds (venous and arterial ulcers, diabetic ulcers and pressure ulcers), postoperative dehisced wounds and traumatic wounds.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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## 510(k) Summary

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| **Submitter:** | Martin Spengler, Head of Regulatory Affairs, Legal Manufacturer Hamburg<br>BSN medical GmbH<br>Quickbornstraße 24, Hamburg, 20253 Germany<br>Phone: +49 (040) 4909-7233<br>Fax: +49 (040) 4909-5476 |
| **Contact Person:** | Marcia Palma<br>Senior Principle Regulatory Consultant, NAMSA<br>4050 Olson Memorial Hwy, Suite 450 Minneapolis, MN 55422<br>Telephone: 763.588.9847<br>Fax: 763-287-3836<br>Email: mpalma@namsa.com |
| **Date Prepared:** | January 22, 2015 |
| **Trade Name:** | Cutimed® Sorbact® Wound Dressings (Cutimed® Sorbact® Hydroactive, Cutimed® Sorbact® Hydroactive B, Cutimed® Siltec Sorbact®) |
| **Classification:** | Unclassified |
| **Product Code:** | FRO |
| **Predicate Device(s):** | The subject device is equivalent to the following device:<br>K063059, Sorbact® Wound Dressings, Abigo Medical AB |
| **Device Description:** | Cutimed® Sorbact® Wound Dressings combine Sorbact mesh (Sorbact acetate fabric coated with dialkylcarbamoylchloride - DACC) with a highly absorbent hydropolymer matrix or superabsorbent polyurethane foam and are covered by a semi-permeable polyurethane film. A fixation border is made of a latex free hydrogel or silicone adhesive. The dressings come in three models (Cutimed® Sorbact® Hydroactive, Cutimed® Sorbact® Hydroactive B, Cutimed® Siltec Sorbact®), multiple sizes in each model and are sterile and single use. |
| **Intended Use:** | Cutimed® Sorbact® Hydroactive is indicated for use in the management of low to moderate exuding partial to full thickness wounds (including clean, colonized, contaminated, or infected wounds): chronic wounds (venous and arterial ulcers, diabetic ulcers and pressure ulcers), postoperative dehisced wounds and traumatic wounds.<br><br>Cutimed® Sorbact® Hydroactive B is indicated for use in the management of low to moderate exuding partial to full thickness wounds (including clean, colonized, contaminated, or infected |

<table>
<tr><td></td><td colspan="3">wounds): chronic wounds (venous and arterial ulcers, diabetic ulcers and pressure ulcers), postoperative dehisced wounds and traumatic wounds.<br><br>Cutimed® Siltec Sorbact® is indicated for use in the management of moderate to heavily exuding partial to full thickness wounds (including clean, colonized, contaminated, or infected wounds): chronic wounds (venous and arterial ulcers, diabetic ulcers and pressure ulcers), postoperative dehisced wounds and traumatic wounds.</td></tr>
<tr><td>Comparison to Predicate:</td><td>Product</td><td>Cutimed® Sorbact® Wound Dressings</td><td>Predicate: Sorbact® Wound Dressings</td></tr>
<tr><td></td><td>Indications for Use</td><td>Cutimed® Sorbact® Hydroactive is indicated for use in the management of low to moderate exuding partial to full thickness wounds (including clean, colonized, contaminated, or infected wounds): chronic wounds (venous and arterial ulcers, diabetic ulcers and pressure ulcers), postoperative dehisced wounds and traumatic wounds.<br><br>Cutimed® Sorbact® Hydroactive B is indicated for use in the management of low to moderate exuding partial to full thickness wounds (including clean, colonized, contaminated, or infected wounds): chronic wounds (venous and arterial ulcers, diabetic ulcers and pressure ulcers), postoperative dehisced wounds and traumatic wounds.<br><br>Cutimed® Siltec Sorbact® is indicated for use in the management of moderate to heavily exuding partial to full thickness wounds (including clean, colonized, contaminated, or infected wounds): chronic wounds (venous and arterial ulcers, diabetic ulcers and pressure ulcers), postoperative dehisced wounds and traumatic wounds.</td><td>Sorbact® Wound Dressings are intended for use in the management of moderate to heavily exuding partial to full thickness wounds (including clean, colonized, contaminated, or infected wounds) and to bind hydrophobic microbes. The dressings are indicated for post-operative wounds, trauma wounds, shallow cavity wounds, fistulas, pressure ulcers, diabetic ulcers, and venous ulcers.</td></tr>
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| | Device Design | The Cutimed® Sorbact® Wound Dressings are designed with an acetate fabric coated with DACC (Sorbact®) in combination with an absorbent core, which absorbs and locks exudate from the wound, and a transparent semi-permeable polyurethane film to allow vapor and oxygen to penetrate the film. It is also designed with an adhesive layer for fixation (except the Hydroactive dressing). | Same |
| | Wound Contact Material | Sorbact mesh (Sorbact acetate fabric coated with dialkylcarbamoylchloride – DACC) | Same |
| | Exudate Absorption Material | Hydropolymer matrix or polyurethane foam | Non-woven Viscose |
| | Transparent Semi-permeable backing | Polyurethane film | Same |
| | Self Adhesive Border | Yes (Except Cutimed® Sorbact® Hydroactive) | Same |
| | Mechanism of Action | Used for the management of clean, colonized, contaminated, or infected wounds; rapidly absorbs and locks exudate within an absorbent core; allows water vapor and gases to evaporate from the skin to the outside protecting the skin from maceration | Same |
| | Sizes | Multiple sizes | Same |
| | Wear Time | Up to 4 days | Change at least twice per week |
| | Sterility | Gamma radiation (SAL $10^{-6}$) for Cutimed® Sorbact® Hydroactive and Cutimed® Sorbact® Hydroactive B; EO (SAL $10^{-6}$) for Cutimed® Siltec Sorbact® | Gamma radiation (SAL $10^{-6}$) |
| | Single Use | Yes | Same |
| | Storage Conditions | Dry, below 25°C | Same |
| | Shelf Life | 3 years | 5 years |
| | Latex Free | Yes | Same |
| | Biocompatible | Yes | Same |
| **Functional and Safety Testing:** | To verify that device design met its functional performance and safety requirements, representative samples of the device | | |

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| | underwent testing including bench testing (absorption, MVTR, retention), biocompatibility testing (cytotoxicity, irritation, sensitization, systemic toxicity, implantation, genotoxicity), packaging testing (pouch seal and transportation), sterilization validation testing, and stability testing (AA and real time). |
| **Conclusion:** | BSN medical GmbH considers the Cutimed® Sorbact® Wound Dressings to be equivalent to the predicate device listed above. This conclusion is based upon the device's similarities in intended use, design, mechanisms of action, technology and materials. |